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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,420	02/19/2004	Timothy G. Laske	P-10756.02	6294

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EXAMINER	
SMITH, TERRI L	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 09/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/782,420	LASKE ET AL.	
	Examiner	Art Unit	
	Terri L. Smith	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 February 2006 and 01 December 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7-29-04,9-17-04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed on 17 September 2004 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because Applicant did not submit entry BF for consideration. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because a) reference character "2" (Figure 1) has been used to designate both right atrium and atrioventricular node; and b) reference characters "262" and "263" have both been used to designate anchoring tine. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office Action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the Examiner, the Applicant will be notified and informed of any required corrective action in the next Office Action. The objection to the drawings will not be held in abeyance.

Specification

3. The disclosure is objected to because of the following informalities: The references to "Figure 4" (page 3, paragraph 12, line 1 and page 1, paragraph 42, line 8) are not shown in the drawings. The drawings contain Figures 4A, 4B, 4C, and 4D, but not Figure 4.

On page 5, the references to "right atrium 10"and "right atrium (RA) 10" (paragraph 31, lines 3, 7, 8 and 20) are not shown in Figure 1 as stated. Rather, Figure 1 depicts the right atrium as reference character 2.

The reference to "Figure 8" (on page 13, paragraph 47, line 4) is not shown in the drawings. The drawings contain Figures 8A and 8B, but not Figure 8.

On page 14, the discussion that references Figure 9B (paragraph 48, lines 2–5) does not pertain to Figure 9B. It appears that the reference should be Figure 9A.

On page 15, the reference to "arrow F" (line 12) is not shown in the drawings.

On page 17, the reference to "Figure 11" (line 10) is not shown in the drawings. The drawings contain Figures 11A and 11B, but not Figure 11.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the Applicant regards as his invention.

5. Claims 1–7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Claim 1 is rejected as being incomplete for omitting essential steps for calculating a ratio of P-wave amplitude to R-wave amplitude and deciding/determining when the ratio and

the pacing threshold meet the stated limitations prior to selecting from one or more positions an electrode implant site.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1–6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Salo et al., U.S. Patent 5,728,140 in view of Gryzwa et al., U.S. Patent 6,473,649.

9. Regarding claim 1, Salo et al. disclose inserting a single electrode or a pair of electrodes into an interventricular septal zone (column 1, lines 51–53; column 3, lines 55–56), which is in proximity to the bundle of His where pacing stimulation results in a rhythm breaking out at an intrinsic location (Figs. 1–2, element 18; column 3, lines 55–57); positioning a single electrode or pair of electrodes at one or more positions within a septal zone (Fig. 1, element 18); sensing by means of a single electrode or pair of electrodes at one or more positions (column 6, lines 46–

49); pacing by means of a single electrode or pair of electrodes at one or more positions (ABSTRACT, lines 1–2; column 5, lines 52–54); selecting from one or more positions an electrode implant site (Fig. 1, element 18); and implanting a single electrode or pair of electrodes at a selected site to deliver physiological pacing (Fig. 1, element 18). Salo et al. do not disclose measuring a P-wave amplitude and an R-wave amplitude sensed at each position; measuring a pacing threshold of a single electrode or pair of electrodes at each position; a ratio of P-wave amplitude to R-wave amplitude is less than approximately 0.5. However, Gryzwa et al. disclose measuring a P-wave amplitude (Fig. 31, element 392; column 24, line 42) and an R-wave amplitude (Fig. 29, element 352; column 22, line 24) sensed at each position to provide optimum noise attenuation for optimum cardiac rhythm management; measuring a pacing threshold of a single electrode or pair of electrodes at each position (column 18, lines 47–49) to increase the pacing safety margin for optimum cardiac rhythm management; a ratio of P-wave amplitude to R-wave amplitude is less than approximately 0.5 (column 4, lines 49 –52, where a ratio is a P-wave of 1 mV over an R-wave of 5 mV that renders a ratio of .2 (1mV/5mV=.2)) to enhance the cardiac rhythm management device's ability to accurately identify evoked potential in spite of afterpotential. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Salo et al. to include measuring a P-wave amplitude and an R-wave amplitude sensed at each position; measuring a pacing threshold of a single electrode or pair of electrodes at each position; a ratio of P-wave amplitude to R-wave amplitude is less than approximately 0.5, as taught by Gryzwa et al. to provide optimum noise attenuation for optimum cardiac rhythm management and to increase the pacing safety margin for optimum cardiac rhythm management and to enhance the cardiac rhythm

management device's ability to accurately identify evoked potential in spite of afterpotential. Salo et al. and Gryzwa et al. disclose the essential features of the claimed invention except for a pacing threshold is less than or equal to approximately 1.5 volts. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a pacing threshold is less than or equal to approximately 1.5 volts, since it has been held that where the general condition of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

10. Salo et al. disclose positioning a single electrode or pair of electrodes at one or more positions comprises varying an insertion depth (claim 2) (column 4, lines 55–56), re-inserting the single electrode or pair of electrodes (claim 3) (column 6, lines 40–41); a single electrode or pair of electrodes are included in an array of electrodes (column 3, line 62–column 4, lines 1–7) and a step of positioning a single electrode or pair of electrodes at one or more positions comprises selecting a single electrode or pair of electrodes from an array at each of the one or more positions (column 4, lines 48–50) (claim 4); a step of inserting a single electrode or pair of electrodes comprises advancing a single electrode or pair of electrodes endocardially through a right atrium (claim 5) (Fig. 1) and a right ventricle (claim 6) (Fig. 1).

11. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Salo et al., U.S. Patent 5,728,140 and Gryzwa et al., U.S. Patent 6,473,649, and further in view of Ding et al., U.S. Patent Application Publication 2003/0105492.

12. Salo et al. and Gryzwa et al. disclose the essential features of the claimed invention except for advancing a single electrode or pair of electrodes epicardially. However, Ding et al. disclose advancing a single electrode or pair of electrodes epicardially (paragraph [0019], lines

2–3) to provide ease of recording an epicardial electrogram for optimum cardiac rhythm management signal acquisition. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the modified inventions of Salo et al. and Gryzwa et al. to include advancing a single electrode or pair of electrodes epicardially to provide ease of recording an epicardial electrogram for optimum cardiac rhythm management signal acquisition.

Conclusion

13. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Terri L. Smith whose telephone number is 571-272-7146. The Examiner can normally be reached on Monday - Friday, between 7:30 a.m. - 4:00 p.m..

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TLS
September 21, 2006

21 September 2006

GEORGE R. EVANISKO
PRIMARY EXAMINER
9/21/06